WORK INSTRUCTIONS FOR DEVICE DESIGN RISK MANAGEMENT

Version	Summary of Change	Form Changed?
5	Consolidated OP650-010 into PR602-003 and put document into work instructions format; Changed reference to PR800-011 and –012 for Design Control; Clarify role of Independent Observer with regard to reviewing a risk assessment; Clarify Conceptual DDSA requirements; Add requirement for DDSA to reflect against design version; Update Quantitative & Qualitative Characteristics Worksheet; Remove defect classifications from Risk Levels; Update App. V, Guideline for Identification of Possible Hazards; Update App. VII, Risk of Harm (Severity) Ranking Scales; Remove old App. X, Split App. II to create new App. X. (DCP #CP2002ANS006)	Yes
6	Typographical error correction on Numbering for Appendix IV	Yes

** Changes
/// Deletions

SCOPE This document applies to all associates at domestic Ethicon, Inc. facilities, the Ethicon, San Lorenzo, Puerto Rico facility, and to Ethicon, Inc. in Juarez, Mexico, who impact the design of new or existing products.

When ETHICON is the manufacturer of a medical device, custom-made device, or accessory, the requirements defined by this procedure must be completed prior to first human use.

The DDSA serves as the foundation for assessment of device design risk.

This document defines the device risk assessment procedure as applied to a new or modified product design.

The role of device design risk analysis is to provide a useful tool in identifying health and safety problems and approaches to their solution, facilitating objective decisions on the acceptability of risk, and meeting regulatory requirements.

This procedure applies to the evaluation of hazards, and their risk(s), as associated to product design.

EXHIBIT

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- Identification of anticipated and unanticipated use-related hazards.
- Construction of use-related scenarios in which hazards could arise.
- Development of strategies to control use-related hazards.

Risk Management culminates in a demonstration of safe and effective device use through the design validation process (PR800-011 for new devices; PR800-012 for modified devices).

OVERVIEW Design risk management is the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling and monitoring risk.

Due to the importance of the medical device user and patient's safety, the description of design risk management in this procedure is directed to device safety.

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This procedure provides the requirements for conducting, documenting, and approving a Device Design Safety Assessment (DDSA).

Risk management activities include:

- Program planning.
- Setting risk criteria.
- Identifying hazards and Failure Modes
- Risk assessment.
- Risk reduction and control.
- Documentation.

5 Responsibilities

Responsibility	Activity
Vice President Regulatory Affairs / Quality Assurance	• Responsible for the Device Design Risk Management Program
Project Leader	Ensure that the • Product's risk assessment activity is contained within the Project Plan, • Risk assessment is completed prior to the Final Design Review, • Review of the approved DDSA report is included in the agenda of the Final Design Review (if the approved DDSA report has not been reviewed at a previous Design Review).

Responsibility	Activity
New Product Development Quality Assurance Engineering	• Lead the team in the device risk management process, • Appropriate departmental functions are represented, • Risk management activities are documented in accordance to procedures, • Recommended Actions, if appropriate, are followed-up, verified and implemented. • Review pertinent activities of the meeting with the responsible function, in the event that a responsible function cannot attend the DDSA meeting(s). • Document the DDSA, as defined by this procedure. • Obtain the Medical Director's, or delegates, approval on the final version of the Device Design Safety Assessment (DDSA) report. • Conduct a semi-annual review of the Device Design Safety Assessment (DDSA) report against the Product Complaint database for the presence of new hazards and frequencies of occurrence for a period of not less than two year after a new product is launched. • Document this semi-annual review. Documentation shall be forwarded to RDCF for filing in the project's Risk Management documentation archived within the Design History File or Electronic Design History File of the product, if appropriate, • Reconvene the risk assessment team in the event discrepancies in the DDSA are noted through this review process. • Conclude that the DDSA discrepancies are related to the product's manufacturing process, initiate a CPAS-event related to the trend. Document the conclusions of the team in the DDSA review report, and disband the team.

Responsibility	Activity
Project Team / DDSA Team	• Participate in the device design risk management process. (Note: The Device Design Safety Assessment team should possess the intimate knowledge of the design, manufacture, and the methodology for use of the product and historical equivalents.) • Conclude whether the device is adequately safe or not, and signify consent by approval signature on the DDSA approval page (Appendix I). • In the event that the NPD QAE reconvenes the team post-launch due to discrepancies in the DDSA, determine if the source of the DDSA discrepancies are resultant of either the product's design (which includes user error/training) and/or the product's manufacturing process. • Resolve the DDSA discrepancy, if the team concludes that the DDSA discrepancies are related to the product's design or to the DDSA itself.

Independent Observer for Design Review	• Assess the adequacy of the DDSA:
	  • Verify that the scope of the DDSA is appropriate for the device's stated objective(s).
	  • Concur that all assumptions are credible in light of available information.
	  • Verify that the data utilized to support the DDSA rankings is appropriate, and presented in a manner which does not diminish or minimize the potential risk/hazard for which the data was generated, such as graphically presenting data with inappropriate scales.

Management: - Director of Medical Affairs for the Business Unit - Director of RA/QA for the Business Unit - Director of Operations/R&D if impacted	• Review product-development risk issues as defined within this and related procedures (OP650-011), for the purpose of accepting the team's Risk Management Control Plan, should the risk assessment result in a Risk Level IV or V hazard.

FLOWCHART

Procedure for Device Design Risk Management

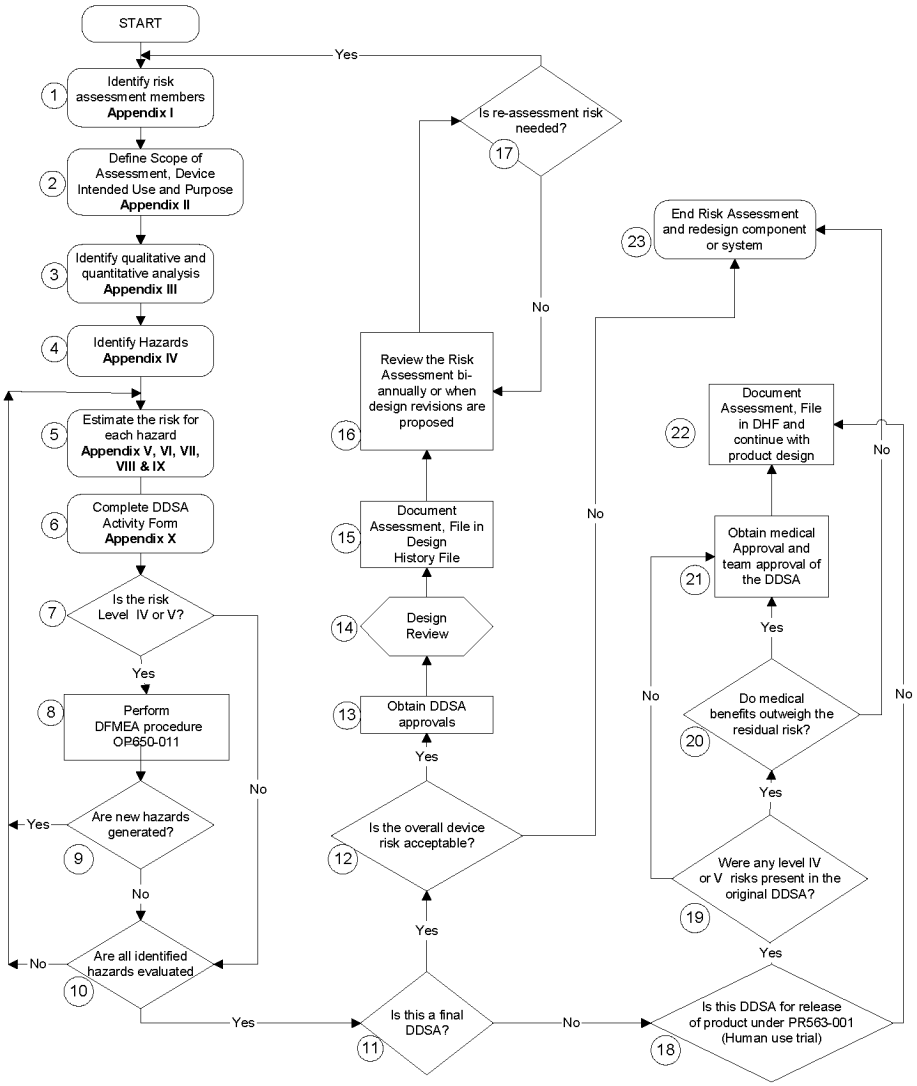

Figure A: Risk Management Process Flow diagram

PROCEDURE AND REQUIREMENTS

1. Identify risk assessment members (Appendix I)	
• Create a "core" team of 3-4 associates, and utilizing other expertise as and when needed.	
Requirements	
• The "core" team should possess the intimate knowledge of the design, manufacture, and the methodology for use of the product and historical equivalents.	
• Assessment (DDSA) team shall consist of the following functional representatives	
Responsibility	**Requirement**
Product Development	Core Team Member
Manufacturing Engineering/ Technical Services	Core Team Member
Quality Assurance Engineer	Core Team Member
Regulatory Affairs	Core Team Member
Product Inquiry	As needed
Clinical Affairs	As needed
Marketing	As needed
Purchasing	As needed
Test Development Engineer	As needed

2. Defining the Scope of Assessment, Device Intended Use and purpose (Appendix II)
• Define and document the scope of the DDSA (Device Design Safety Assessment) at the initiation of the risk analysis.
Requirements

• The DDSA Summary Report includes, but is not limited to:
  • Device
  • A complete description and identification of the device(s), sub-system or accessory.
  • Scope
  • A definition of both physical and functional boundaries.
  • A definition of the environment where the system could be used.
  • A definition of all flows and influences that cross

boundaries.
- A definition of the operating conditions covered by the DDSA and any relevant limitations.
- Provide details of all the technical, environmental, organizational, and human circumstances that are relevant to the activity and the system being analyzed, particularly any circumstances related to safety.
- State the assumptions and constraints governing the analysis.
- Identify the decisions that have to be made, the criteria for these decisions, and the decision-makers.

- Medical Impact

3. Identify qualitative and quantitative analysis (Appendix III)

- Identify all of the product's characteristics that *could* impact its safety within the constraints of the device's intended use, and specify the defined limits by completing the Quantitative & Qualitative Characteristics Worksheet (Appendix III).

- Identify and append additional characteristics to the Quantitative & Qualitative Characteristics Worksheet (Appendix III), in the event that the Quantitative & Qualitative Characteristics Worksheet does not contain all of the appropriate device characteristics as defined by the Scope of the DDSA,

- Document whether each characteristic is appropriate to the device as constrained by the Scope of the DDSA.
  - Place a mark in the "N/A" column if a characteristic is not appropriate to the device defined by the Scope of the DDSA.
  - Place a mark in the "YES" column if a characteristic is appropriate to the device defined by the Scope of the DDSA.
    - When the "YES" column is marked, the "Comment" column needs to be addressed by:
      - Appending appropriate documentation to the Worksheet; or
      - Providing an indicator to the location of the documentation which may reside in RDCF (Research & Development Central File), DHF (Design History File), Laboratory Notebook, Risk Management File, or other appropriate means

- File the Quantitative & Qualitative Characteristics Worksheet in the Risk Assessment documents in the Design History File

Requirements

- A completed Appendix III must be filed in the DHF.

4. Identify Hazards (Appendix IV)	

• Complete the Use Related Hazards worksheet (Appendix IV).
  • If a "grayed" box in Appendix IV is marked with an "X", then the steps identified at the bottom of the worksheet must be utilized to appraise the potential misuse hazard across the intended users.
  • File the Use Related Hazard Worksheet and subsequent resulting documentation in the DHF.	

• Identify unanticipated use conditions using the intended context for use, or realistic use environments, empirical techniques, such as usability testing.	

• Have prototypes and any supporting documentation at the device risk assessment if they are available.
  • Use a walk-through to guide a user or small group of users through the process of using the device. During the walk-through, participants are questioned and encouraged to provide feedback on difficulties they notice while using the device.
  • Dependent upon the complexity of the product, a "walk-through" evaluation may not be sufficient. A more extensive usability test, involving the systematic observation and collection of performance and subjective data from actual users using a device (or device component), may be needed.
  • Test coordinators should provide general and specific instructions on how to use the device as necessary, develop test scenarios for use, recruit and instruct test participants, and develop data collection and analysis methodologies.	

• Analyze resulting data to identify use scenarios resulting in hazards and recommend specific actions to address them.	
Requirements	
• The hazards associated with the device under review must be evaluated within the context of both normal/typical operations, in addition to fault-condition operation. In addition, potential user misuse of the system, device, or accessory must be considered.	
• Anticipated Use Scenarios	Use analytical techniques to: • Expand the information from device use description • Review and identify safety-critical user actions • Use scenarios resulting in

	hazards • Understanding the context under which these can occur for typical use conditions.
• Unanticipated Use Scenarios:	Use the following to identify conditions: • Intended context for use, or realistic use environments • Empirical techniques, such as usability testing

• Usability testing can be done in a variety of ways in various degrees of complexity and formality but must include:
  • Test participants represent intended users of the device.
  • Test participants do real tasks, particularly tasks that best reflect whether safe and effective use is occurring.
  • Testers observe and record important aspects of what test participants do and say (participants may also respond to questionnaires).
• Usability testing coordinators should:
  • Provide general and specific instructions on how to use the device as necessary
  • Develop test scenarios for use
  • Recruit and instruct test participants
  • Develop data collection
  • Analysis methodologies	

5. Estimate the risk for each hazard (Appendix V, VI, VII, VIII, & IX)
• Review the Guideline for Identification of Possible Hazards (Appendix V), and generate a pertinent hazard list using the DDSA Form (Appendix VI) column labeled "Hazard."

• Document the potential hazards associated with the device operating in both normal and failed (fault) operating conditions.
  • Hazards will be limited to appropriateness as defined by the device's intended use.
  • In determining whether a hazard is applicable, evaluate the failure potential in lieu of "Normal use, worst case."
  • Document assumptions, such as "intended use", "expertise" of the intended user, etc.

• Classify each hazard according to whether it is caused by random failure (i.e., fault condition or misuse) or systemic failure (i.e.,

normal use).

• Designate each identified hazard in the "Fault Class" column of DDSA Form (Appendix VI) with the following:
  • N: Occurs during normal conditions. (Does the hazard occur in the absence of failure?)
  • S: Occurs as a single fault condition. (Does the hazard occur in failure only?)
  • C: Occurs only as a combination of faults. (Does the hazard occur only in a multiple fault condition?)
  • M: Occurs through incorrect or misuse. (Does the hazard occur through misuse of the product?)

• Estimate the risk for both normal and fault operating conditions using available information and data, as defined by the intended usage of the device, for each of the hazards identified.
• Score the severity of the resulting possible harm according to the Risk of Harm Ranking for DDSA (Appendix VII) and recording in the column labeled "Severity of Harm" on the DDSA Form (Appendix VI).
• Score the probability of the hazard according to the scale in the Likelihood of Hazard Rankings for DDSA (Appendix VIII), and record in the column labeled "Probability of Hazard" on the DDSA Form (Appendix VI).
• Designate the risk associated with each hazard as Risk Level I, II, III, IV, or V, per the Assignment of Risk Level for DDSA (Appendix IX). Determine the risk level from the intersection of Severity with Probability Rankings in Appendix IX. Record in the column labeled "Risk Level" of the DDSA Form (Appendix VI).

• If a similar device system is used for the risk assessment instead of the actual device, the team must demonstrate that:
  • The design functions of the similar systems are comparable, or
  • The changes that have been made to the current system will not introduce significant differences in the results of the device risk assessment.
  • The comparison will be based upon a systematic evaluation of the design/functional changes, and the way they can influence the various hazards present.
  • Clinical evidence
  • Results of appropriate investigations

• Archive all documentation in the Design History File.

Requirements

• Risk estimation should consider the following to generate a measure for the level of risk being analyzed:
  • Events or circumstances which initiate the hazard;
  • Sequence of events leading to the hazard;
  • Mitigating features (controls) which could potentially minimize the risk;
  • The source and potential rate of occurrence of the possible consequences of the identified hazard

• Information and data for estimating risk may be, but are not limited to:
  • Relevant standards
  • If the risk for a hazard is addressed by compliance with a published standard, the risk is deemed acceptable at the current state of the art and no further analysis of this risk is required.
  • Scientific data
  • Field data from similar devices

6. Complete the DDSA Activity Form (Appendix X)
• Complete Appendix X after the completion of Appendices I to IX.
• Document whether each activity is completed or not, and reference the appropriate file to the activity as per Appendix X of the DDSA by filling the appropriate column
• Place a "YES" in the column if the activity is completed or appropriate to the device.
• Reference appropriate documentation on the Worksheet or provide a location of the appropriate reference
• Place a "N/A" in the column if the activity is not required or applicable to the device   • The "Comment" column needs to be addressed for every line
• File the completed Appendix X in the DHF.
Requirements
• The activity form Appendix X must be completed during the DDSA process.

7. Is the risk level IV or V?	
IF	**THEN**
No	Go to step 10
• Risk Level III - Risk is acceptable. This hazard needs to be revisited in future designs if corrective actions enhance the device's reliability. • Risk Level II - Risk acceptable. No actions required. • Risk Level I – No risk associated with the hazard. No actions required.	
Yes	Go to step 8.
• Perform DFMEA	

8. Perform DFMEA Procedure (OP650-011)	
• Follow OP650-011, Operating procedure for design failure modes and effects analysis (dFMEA)	
Requirements	

• If the device risk estimation process results in a risk of Level IV or V, then the hazard in question must be subjected to risk reduction analysis using suitable techniques. A documented Recommended Action Plan and Corrective Action Plan are required. Verification of the adequacy of the Corrective Action Plan must be performed and documented.
  • An alternate method of risk analysis and mitigation may be used if the team decides it is more appropriate than a DFMEA.
  • If an alternate method is used and risk levels are not reduced below DDSA levels IV or V, a Control plan is required, and management approval of the Control plan must be documented.
  • All activities from the alternate method must be documented and filed in the Design History File.	

• OP650-011 defines the design Failure Modes and Effects Analysis (DFMEA) risk analysis and reduction process.	

9. Are new hazards generated?	
IF	**THEN**
Yes.	Go to step 5
• Conduct a review of the DDSA to determine whether the risk reduction activities have introduced any new hazards per Identification of User Related Hazards, step 4.	
No	Go to step 10

• Go on to check whether all identified hazards have been evaluated.	

10. Are all identified hazards evaluated?	
IF	**THEN**
Yes.	Go to step 11
• Every risk identified in step 4 has been assessed.	
No	Go to step 5
• Go back and analyze the next hazard on the list.	

11. Is this a final DDSA?	
IF	**THEN**
Yes.	Go to step 12
• Go on to evaluating overall risk.	
No	Go to step 18
• Go on to evaluate whether this product is for human use trial.	

12. Is the overall device risk acceptable?	
IF	**THEN**
Yes.	Go to step 13
• The team assessing design risk must conclude the assessment with a decision whether or not the reviewed device risk is acceptable for its intended use.	
No	Go to step 23
• If the team concludes that there is too much residual risk and the device is unacceptable, go on to end the risk assessment.	

13. Obtain DDSA approval
• Have each core team member signify consent by signing the DDSA Approval Page (Appendix I).
• Have the Medical Affairs Director, or delegate, approve the final version DDSA report, after approval by the risk assessment team core members.
• Upon approval by Medical Affairs, control and archive the Risk Assessment documents in the product's Design History File.

Requirements
• The Medical Affairs Director's, or delegate's, approval signifies concurrence with the clinical judgments associated with each identified hazard.

14. Design Review
• Conduct a formal review to confirm the integrity and correctness of the DDSA process as part of a Design Review.
Requirements
• The DDSA must be approved prior to Design Transfer or first human use.

15. Document Assessment, File in Design History File
• Document and file all design-related activities associated with the risk management process in the Design History File for the product.

Requirements

• The Risk Assessment documents are controlled documents.
  • The following contents are a list of Risk Assessment outputs and constitute a subsection of the device's Design History File:
  • All versions of the DDSA report.
  • Identification of DDSA Team Members and functional area of responsibility (Appendix I).
  • Approved DDSA Approval Page (Appendix I).
  • Completed DDSA Summary Report (Appendix II).
  • Identification of device Qualitative and Quantitative Device Characteristics (Appendix III).
  • Use Related Hazards (Appendix IV).
  • In the event that a usability test is required, a summary report with the raw data appended must be included
  • Identification of possible hazards and associated risks (Appendix VI).
  • Risk reduction documentation, if required per DFMEA.
  • Suitable methodology to document risk reduction, such as DFMEA (reference OP650-011).
  • Recommended Action Plan and Corrective Action Plan if appropriate per DFMEA.
  • Control Plan, if appropriate per DFMEA.
  • Records of each post-launch review.
  • Revisions to the Device Design Safety Assessment must be identified with a revision date, version number, and is archived in the Design History File.
  • Identification of the design version of the product/sub-system/component that is being assessed.

16. Review the Risk Assessment bi-annually or when design revisions are proposed
• Review and update the Risk Assessment section of the DHF as new information becomes available from either post-production usage data; i.e. hazards and frequency of occurrence, or a modification to the device design.
• Review the DDSA report if a design revision is proposed, to ensure that all proposed design revisions will not create any new hazards related to the use of the product and/or impact the established risk levels from previously identified hazards.

• The New Product Development Quality Assurance Engineer will review the Risk Assessment section of the DHF, including the DDSA report and risk reduction report (as appropriate) on a regular basis, at a minimum of every six months post-launch for a period of not less than two years.
• Investigate the product complaint data regarding the incidence of new hazards and frequency of their occurrence against the final version Risk Assessment documents of the product.
Requirements
• Each revision to the product's or component's design, within the boundaries defined by the DDSA's Scope (Summary Report, Appendix II), requires a re-evaluation of the DDSA.
• All revisions must be documented in the Design History File.

17. Is re-assessment of risk needed?	
IF	**THEN**
Yes.	Go to step 1

• If a proposed product revision is outside the boundaries defined by the DDSA's Scope (Summary Report, Appendix II), such as a new intended use, intended user, or medical impact, then a new risk assessment is required.
• In the event that an unforeseen complaint occurs in the Product Complaint database that is not captured in the existing Risk Assessment documents, an investigation into the root cause must be conducted.
  • Possible results from this investigation could be:
  • Repeat the design device risk assessment for those affected hazards and take appropriate action.
  • Educate the user.
  • Change the device design.	

No	Go to step 16
• Continue updates on a 6-month basis or as design revisions are proposed	

18. Is this DDSA for the release of product under PR563-001 (Human use trial)?	
IF	**THEN**
Yes	Go to step 19
• The device is to be released per PR563-001 for human use (such as surgeon preference or clinical study).	
No	Go to step 22
• Go on to document the assessment	

19. Were any level IV or V risks present in the original DDSA?	
IF	**THEN**
Yes.	Go to step 20
• The team assessing design risk must conclude the assessment with a decision whether or not the reviewed device is safe for its intended use. If any level IV or V risks remain, go on to evaluate the potential medical benefits.	
No	Go to step 21
• If the product is deemed safe, continue with obtaining medical approval.	

20. Do the medical benefits outweigh the risks?	
IF	**THEN**
Yes	Step 21
• Risk is acceptable only if it cannot be further mitigated by organizational or technological controls that do not reduce the clinical or functional utility of the device. • If the team decides that the medical benefits of the device outweigh the risk, the risk assessment must contain the documentation that supports this position. • Go on to get medical approval.	
No	Step 23
• If the medical benefits do not outweigh the risk of the device, go on to end the risk assessment.	

21. Obtain Medical and Team approval of the DDSA
• Have Appendix I signed by all parties so that the device can be released for human use trials.

Requirements
• DDSA must be completed and approved by all parties (Appendix I) prior to the approval of the subject PR563-001 form.

22. Document Assessment, file in DHF and continue with product design
• Document all risk assessment activities and file them in the Design History File.
• Continue to review and update all risk assessment documents as needed as the device design progresses.
Requirements
• The risk assessment activities conducted at all levels of development must be documented and filed in the DHF.

23. End risk assessment and redesign component or system.
• Redesign the device so as to mitigate its current unacceptable levels of risk.   • Conduct a revised DDSA regarding the design modification and the impact of the changes upon any aspect of the device's performance if a design modification is made to the device or accessory based upon results from the above studies.
Requirements

• An evaluation of a design modification must be made on whether:
  • The design modification results in the desired outcome, and
  • The design modification does not result in any additional hazards in the labeled/defined use of the device.

REFERENCES

Guide to Medical Device Regulation	FDA Center for Devices and Radiological Health, March 1, 1996.
IEC 513	Fundamental Aspects of Safety Standards for Medical Electrical Equipment.
ISO 14971, Medical Devices - Application of Risk Management to Medical Devices.	CAN/CSA-Q634-91, National Standard of Canada, Risk Analysis Requirements and Guidelines.
ISO 13485, Quality Systems - Medical Devices	Particular Requirements for the Application of ISO 9001.
Design Control Guidance for Medical Device Manufacturers	U.S. Food and Drug Administration, Center for Devices and Radiological Health, March 1, 1996.
U.S. Food and Drug Administration (FDA) Quality System Requirements (QSR)	21 CFR 820.30
ISO/DIS 14971-1	Medical Devices Directive (MDD), Council Directive 93/42/EEC.
International Standards Organization (ISO) 9001	sub clause 4.4.
PR558-001	Document Submission and Approval
PR563-001	Procedure for the Release of Non-Salable Products or Materials Intended for Human Use.
OP650-011	Operating Procedure for Design Failure Modes and Effects Analysis (dFMEA).
PR161-001	Work Instructions for Equipment and Process Change Control Procedure.
PR800-011	Work Instruction for New Product Design Control.
PR800-012	Work Instruction for Design Changes to Existing Product.

DEFINITIONS

Risk Assessment	The process of risk analysis and risk estimation.
Risk Analysis	An investigation to methodically identify hazards, and evaluate and control the risks associated with the design and development of a new or modified product or process.
Risk estimation	The estimation of the likelihood of a hazard and determining of the harm associated with a hazard.
Risk Control	The process of decision-making for managing risk, and the implementation, enforcement, and re-evaluation of its effectiveness from time to time, using the results of risk assessment as one input.
Risk evaluation	The stage in risk management at which values and judgments become part of the decision process, explicitly or implicitly, by including consideration of the importance of the estimated risks and the associated social, environmental, and economic consequences, in order to identify a range of alternatives for managing the risks.
Risk management	The complete process of risk assessment and risk control.
Medical Device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purposes described below, and which do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. ▪ Diagnosis, prevention, monitoring, treatment or alleviation of disease; ▪ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; ▪ Investigation, replacement or modification of the anatomy or of a physiological process; ▪ Control of conception
Accessory	Any article which is intended specifically by its manufacturer to be used together with a device enabling the device to be used in accordance with the intended use of the device.

Custom-made device	Any device specifically made in accordance with a qualified medical practitioners written prescription which gives, under his responsibility, specific design characteristics and is intended for the exclusive use of a particular patient. NOTE: Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user, are not considered to be custom-made devices.
Manufacturer	The company with responsibility for the design, manufacture, packaging, and labeling of a device before it is placed on the market under the companies own name, regardless of whether these operations are carried out by that company directly, or on the companies behalf by a third party.
Harm	Physical injury and/or damage to health.
Hazard	A potential source of harm.
Hazard Identification	The recognition that a hazard exists and the definition of its characteristics.
Risk	The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.
Safety	The freedom from risk.
Probable rate of occurrence	The probability, or likelihood, that a risk involving the device could result in a hazard.
Severity	The seriousness of the harm induced by a hazard.

Device Design Safety Assessment (DDSA)	A technique of device design risk assessment, consisting of identification of the device's characteristics, potential hazards associated with use of the device, and identification of risks associated with each hazard, with an estimation of the risks' frequency and impact, and risk reduction plan, as appropriate. ▪ A concept/initial DDSA is conducted early in the product life cycle, at which time the product criteria, features, mission, and requirements are being developed to compare/evaluate the benefits and tradeoffs of competing design configurations. The conceptual assessment identifies the most obvious failure modes and/or design weak points, and identifies potential single failure points that can be eliminated with minimal engineering effort. ▪ The DDSA is updated, while the device design progresses, such that the DDSA is repeated for the redesigned portions/components of the device system to ensure that all predictable hazards in the design are considered. • A final/product DDSA is the final version of the DDSA, which is the assessment to the final confirmed design.
Final version	The revision of the DDSA (Device Design Safety Assessment) presented and adopted during a Design Review.
Design Failure Modes and Effects Analysis (dFMEA)	A technique, which is primarily qualitative, by which the effects or consequences of an individual component failure modes are systematically identified and evaluated for risk reduction (OP 650-011).
Recommended Action Plan	A plan that provides possible courses of action to reduce a Risk which has an RPN > 294 or a "Δ" resulting from a dFMEA.
Corrective Action Plan	A plan, resulting from investigation of the Recommended Action Plan, which details for each hazard the steps necessary to reduce a risk with an RPN > 294 or with a Δ present to lower the RPN or eliminate the Δ.
Control Plan	A plan which is generated when Risk Reduction activities are unable to lower the RPN to 294 or below or eliminate a "Δ", that summarizes the negotiated requirements to be controlled during manufacturing and inspection.

Fault Mode	A device or system operating condition, in which the device has experienced at least one malfunction.
Device	The item reviewed by the Design Safety Assessment, as defined by the Scope of the DDSA, which may include a product system, sub-system, or component.

APPENDICES

Appendix I	Product DDSA Approval Page
Appendix II	DDSA Summary Report
Appendix III	Quantitative & Qualitative Characteristics Worksheet
Appendix IV	Use Related Hazards
Appendix V	Guideline for Identification of Possible Hazards
Appendix VI	Device Design Safety Assessment (DDSA) Form
Appendix VII	Risk of Harm (Severity) Ranking for DDSA
Appendix VIII	Likelihood of Hazard Ranking for DDSA
Appendix IX	Assignment of Risk Level for DDSA
Appendix X	DDSA Activity Form